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2014

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citation for published version (APA)

van Weyenberg, S. J. B. (2014). *Minimally-invasive imaging of the small intestine*. [PhD-Thesis - Research and graduation internal, Vrije Universiteit Amsterdam].

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Chapter 9

Description of a novel grading system to assess the quality of bowel preparation in video capsule endoscopy

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Endoscopy 2011;43:406–11.

Abstract

Background and study aims

Inadequate bowel preparation negatively influences the reliability of examinations by video capsule endoscopy (VCE). Currently, only subjective scales are available to describe mucosal visibility. We aimed to design a score derived directly from the VCE images.

Patients and methods

A computed assessment of cleansing score was developed based on colour intensities of the tissue colour bar. The feasibility of this score was retrospectively tested in 24 VCE studies. A prospective study was conducted using 40 VCE segments from 10 consecutive VCE studies. The computed scores were compared with three existing methods of assessing small-intestinal cleansing. Correlations between the existing scoring systems and the computed score were evaluated using the intraclass correlation coefficient and Spearman's rho correlation.

Results

All computed measurements were obtained twice and resulted in exactly the same results. Both overall and segmental mucosal visibility could be assessed. The computed score and the 10-point quantitative index were significantly associated for both readers (Spearman's rho, 0.68 and 0.75 respectively; $p < 0.001$). The intraclass correlation coefficient for the four-point qualitative evaluation and the computed score were 0.67 for reader 1 and 0.64 for reader 2. For reader 1, the mean computed score for segments assessed as either inadequate or adequate cleansed segments was 5.0 and 6.4 ($p = 0.001$). For reader 2 these values were 4.0 and 6.3 ($p = 0.005$).

Conclusions

A computed assessment of small-bowel mucosal visibility based on the ratio of colour intensities of the red and green channel of the tissue colour bar is feasible and more reproducible than existing subjective scales. Such a computed scale could be integrated in VCE reading software. For this novel scoring system we propose the term Computed Assessment of Cleansing (CAC) score.

Introduction

Video capsule endoscopy (VCE) enables minimally-invasive examination of the small bowel.¹ The diagnostic yield of VCE is negatively influenced by residual intestinal fluid, air bubbles and food materials.²⁻⁵ Many studies describe the use of several bowel preparations, including polyethylene glycol, sodium phosphate and simethicone, to increase visualisation of the mucosa.⁶⁻¹⁶ Reporting the quality of bowel preparation is not only important to assess the reliability of findings, but also to compare different bowel-cleansing regimens.⁷ Validated scales to assess the quality of small bowel cleansing are scarce and mostly based on subjective parameters.² Therefore a scale directly derived from the VCE images would be useful. Such a scale could possibly also be of use in reporting the quality of bowel preparation for capsule investigation of the colon.^{17, 18}

The aim of our study was to develop a computed quantitative scale to assess mucosal visibility during VCE, and to evaluate the ability of this scale to assess both the overall quality of bowel preparation and the ability of this scale to assess segmental quality of bowel preparation. Finally, we aimed to compare this computed scale with three previously described quantitative and qualitative scales.

Materials and Methods

Design of the computed score

The Rapid software of the reading station (Given Imaging; Yoqneam, Israel) shows a tissue colour bar for identifying anatomical landmarks and maintaining perspective on the location of images. The tissue colour bar comprises a computed summary of colour representations of individual VCE images.¹⁹ We noticed that the tissue colour bar often contains pronounced greenish segments, corresponding to individual VCE images of greenish luminal content. We postulated that if the tissue colour bar was transformed to red-green-blue (RGB) colour mode, the intensity in the green channel in relation to the intensity of the red channel could be used as a measure of small-bowel contamination: Good mucosal visibility could be associated with high values of red intensity and low values of green intensity, whereas faecal contamination could be associated with low values of red intensity and high values of green intensity.

In order to be able to perform measurements of colour intensity, an electronic high-resolution image of the Rapid user interface was captured using commercially available software (Screen Print & Capture 32 3.5; Provtech Limited, West Kilbride, United Kingdom). The image was imported in commercially available photo-editing software (Photoshop CS2 version 9.0.2; Adobe Systems Incorporated, San Jose CA, United States of America) and cropped to contain only the tissue colour bar. Using the histogram option, the mean intensity value of the green and the red channel could be measured within selections of the bar. The red-green ratio was calculated by dividing the intensity of the red channel by the intensity of the green channel.

Experiment 1: Feasibility of assessing the overall quality of small-bowel preparation

For testing the proof of principle, 20 complete VCE studies were randomly selected from our VCE database and de-identified and the complete part of the tissue colour bar representing images from the small bowel was analysed using the method described above. The overall computed score was compared to the endoscopist's overall assessment of preparation (adequate or inadequate) as made during the diagnostic reading of the capsule study.

Experiment 2: Feasibility of assessing segmental quality of bowel preparation

In order to assess the feasibility of segmental scoring, the tissue colour bars of four randomly selected VCE studies were divided into ten equal segments, which were analysed using the method described above.

Experiment 3: Comparison between the computed scale and three previously described quantitative and qualitative scales

The third part of our study was a prospective pilot study aimed to investigate the correlation of the computed score with three previously described subjective methods used to assess bowel preparation. We prospectively included 10 consecutive VCE examinations fulfilling the entry criteria. VCE studies were included if they were performed using the Given Pill cam SB system (Given imaging, Yoqneam, Israel) and if the caecum was reached within the imaging period. All patients received two litres of polyethylene glycol solution (Klean prep; Norgine, Amsterdam, The Netherlands) at midday 1 day before the examination and nil by mouth after midnight before the examination.

After the diagnostic reading, the capsule studies fulfilling the entry criteria were de-identified and renumbered 1 to 10. The capsule studies were then reviewed by one investigator (S. J. B. V. W.) who calculated the small bowel transit time (SBTT). The video images of the small intestine were divided into four segments of equal length, according to SBTT (quartiles) and landmarks were placed to identify the last 10 minutes of every quartile, resulting in four segments of 10 minutes' duration, in each of the ten included VCE studies. The computed score was calculated twice for these segments. Additionally, these segments were independently read by two experienced capsule endoscopists (S. J. B. V. W. and H. T. d. L.), who evaluated the quality of bowel preparation using three different scoring systems: a 10-point quantitative index (0–10), a 4-point qualitative evaluation (poor, fair, good, excellent) and an overall assessment of adequacy (adequate, inadequate) (*box 9.1*). These grading systems were chosen, because they are the only available validated grading systems published in the literature.²

The readers were blinded for findings of previous diagnostic readings, patient characteristics and the results of the computed assessments of cleansing. The capsule studies were viewed with Given Rapid 4 software, version 4.0 (Given Imaging, Yoqneam, Israel) in the DualView at 20 frames/second.

Box 9.1: Overview of the three subjective scales of small-bowel cleansing used in this study.

Quantitative index (QI)

Elements

- Percentage of mucosa visualized *
- Fluid and debris
- Bubbles
- Bile/chyme staining
- Brightness

Score per element †

- 2 = Minimal / mild impairment
- 1 = Moderate impairment
- 0 = Severe impairment

* Severe < 80 = 0, moderate 80%–89% = 1, minimal/mild ≥ 90% = 2.

† Total score = 0–10; higher scores = superior cleansing

Qualitative evaluation (QE)

- Excellent: Visualization of ≥ 90% of mucosa; no, or minimal, fluid and debris, bubbles, and bile/chyme staining; No, or minimal, reduction of brightness.
- Good: Visualization of ≥ 90% of mucosa; mild fluid and debris, bubbles, and bile/chyme staining; mildly reduced brightness.
- Fair: Visualization of < 90% of mucosa; moderate fluid and debris, bubbles, and bile/chyme staining; Moderately reduced brightness.
- Poor: Visualization of < 80% of mucosa; excessive fluid and debris, bubbles, and bile/chyme staining; Severely reduced brightness.

Overall assessment of adequacy (OAA)

- Adequate
- Inadequate

Adapted with permission from Elsevier from Brotz C, Nandi N, Conn M, Daskalakis C, DiMarino M, Infantolino A, et al. A validation study of 3 grading systems to evaluate small-bowel cleansing for wireless capsule endoscopy: a quantitative index, a qualitative evaluation, and an overall adequacy assessment. *Gastrointest Endosc.* 2009;69(2):262-70, 70 e1.

Statistical analysis

The overall computed cleansing scores of the 20 VCE studies included in experiment 1 were categorized according to the adequacy of cleansing as assessed during the diagnostic reading and were compared with two-tailed Student's *t* test. No statistical tests were performed for experiment 2.

In experiment 3, Spearman's correlation was used to describe the correlation between the computed score and the 10-point quantitative index for both readers. Overall agreement between the 4-point qualitative evaluation and the computed score was evaluated using the intraclass correlation coefficient (ICC). Means of computed scores, categorized according to the overall assessment of adequacy per reader, were compared with two-tailed Student's *t* test.

We evaluated the level of agreement between the assessments of preparation by both endoscopists for all three subjective scales used. The ICC was used to assess interreader variability of the 10-point quantitative index and the 4-point qualitative evaluation. The unweighted κ statistic was used to assess the reliability of the overall assessment of adequacy. *P* values < 0.05 were considered to indicate statistical significance.

Results

Experiment 1: Feasibility of assessing the overall quality of small-bowel preparation

The indications for the 20 included VCE examinations to assess the feasibility of computed assessment of the overall quality of preparation were: suspected obscure midgastrointestinal bleeding ($n = 11$), suspected previous overt midgastrointestinal bleeding ($n = 4$), suspected ongoing overt gastrointestinal bleeding ($n = 1$), suspected Crohn's disease ($n = 2$), protein-losing enteropathy ($n = 1$) and carcinoid syndrome ($n = 1$). The mean SBTT of these studies was 274 (range 87–516) minutes. The colour intensity in the red and green channel could be measured in all studies. The mean green intensity ranged from 116 to 167 (mean 144), whereas the mean red intensity ranged from 177 to 245 (mean 220). The red-green ratio ranged from 1.26 to 1.76 (mean 1.53). All colour measurements were obtained twice per segment and resulted in exactly the same results.

We defined the computed score as $([\text{red intensity} / \text{green intensity}] - 1) * 10$. This resulted in overall scores ranging from 2.6 to 7.6 (mean 5.3). The mean computed score of the six examinations regarded during the diagnostical reading to be inadequately prepared was 3.9 (SD 1.0), compared to a computed score of 6.0 (SD 0.9) of the 14 examinations regarded to be adequately prepared ($p = 0.001$).

Experiment 2: Feasibility of assessing segmental quality of bowel preparation

In four VCE examinations the feasibility of segmental computed assessment of cleansing was studied. The mean length of the small bowel segments (10% of SBTT by definition) was 31 minutes (range: 24–38 minutes). The colour intensity in the red and green channel could be measured in all segments. The mean green intensity per small bowel segment ranged from 112 to 207 (mean 144), whereas the mean red intensity per small bowel segment ranged from 169 to 248 (mean 218). The red-green-ratio ranged from 1.18 to 1.77 (mean 1.52). All colour measurements were obtained twice per segment and resulted in exactly the same results. *Figure 9.1* shows the mean red and green intensities of the small bowel segments in relation to the tissue colour bar for all four VCE examinations included in the pilot test. The segmental scores ranged from 1.8 to 7.7 (mean 5.2).

Experiment 3: Comparison between the computed scale and three previously described quantitative and qualitative scales

First, we examined the level of agreement between both VCE readers for each of the three subjective scales used. The mean quantitative index was 7.3 for reader 1 and 7.7 for reader 2 ($p = 0.388$). The interreader reliability for this scoring system was 0.78 (95% CI, 0.62–0.88). The results of the four-point qualitative evaluation for both readers are shown in *table 1*. The interreader reliability for this scoring system was 0.68 (95% CI, 0.47–0.82). Reader 1 judged the bowel preparation to be adequate in 27 (67.5%) of 40 segments, whereas reader 2 judged 5 (12.5%) of 40 segments to be inadequately cleansed. The interreader reliability of this overall assessment was 0.32.

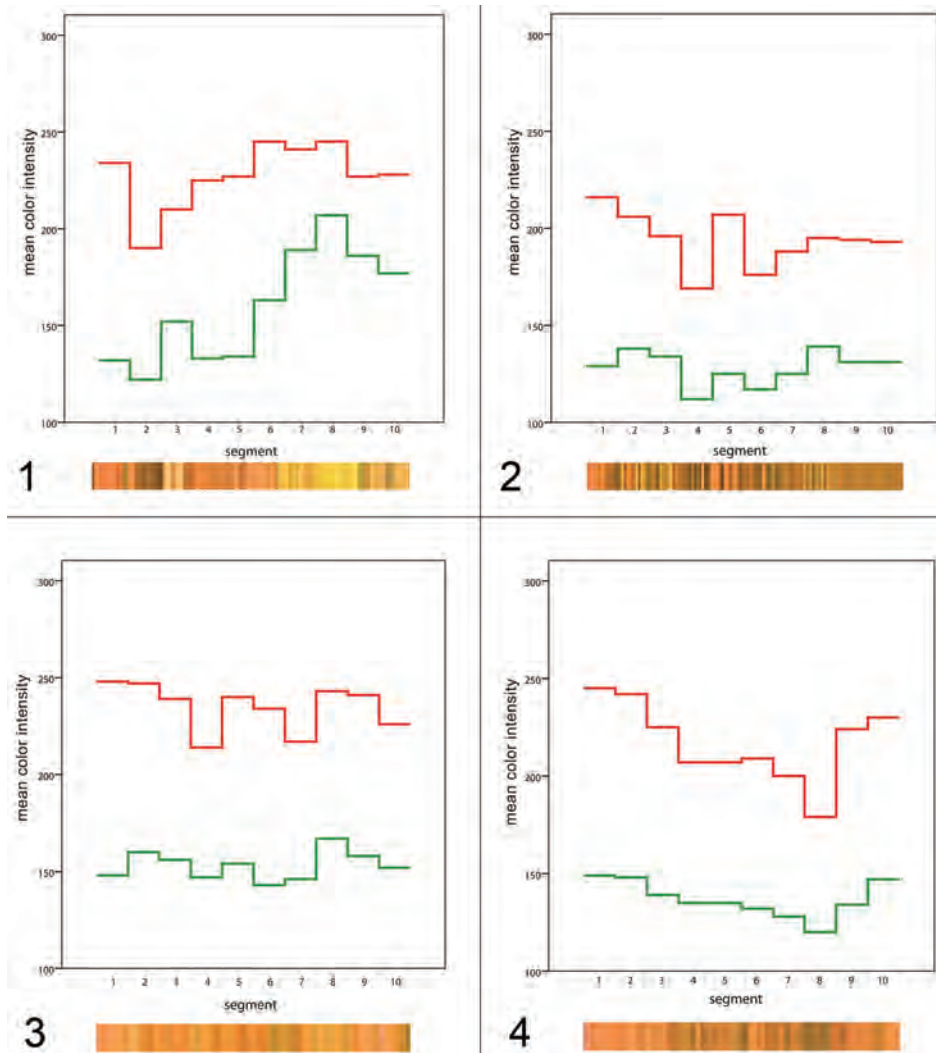
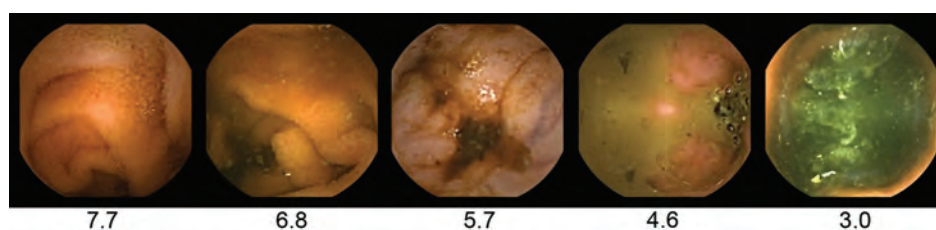


Figure 9.1: Association between the intensities of the red-channel (red line) and green-channel (green line) of each of the four VCE studies included in the proof of principle test. The colour-intensities are presented per segment, representing 10% of the small bowel transit time per segment. Beneath each graph the corresponding tissue-colour bar from passage of the pylorus until passage of the ileocaecal valve is shown.

The computed score could be successfully calculated in all segments. All colour measurements were obtained twice per segment and resulted in exactly the same results, indicating an intratest reliability of 1.0. The mean (SD) computed score of the 40 segments evaluated was 6.0 (1.2). **Figure 9.2** shows representative VCE images from small-intestinal segments with different computed scores.

Table 9.1: Results of the four-point qualitative assessment of cleansing for the 40 small-bowel segments according to reader

		Reader 2: qualitative evaluation				Total
		Poor	Fair	Good	Excellent	
Reader 1: qualitative evaluation	Poor	1	5	0	0	6
	Fair	1	7	0	0	8
	Good	0	5	6	1	12
	Excellent	0	1	9	4	14
	Total	2	18	15	5	40

**Figure 9.2:** Representative VCE images from studies with different computed assessment of cleansing (CAC) scores. The CAC score of the segment from which the image was obtained is shown beneath each VCE image.

The association between the computed score and the 10-point quantitative index for the two VCE readers is shown in *figure 9.3*. For both readers these scores were significantly associated (reader 1: Spearman's rho, 0.68; $p < 0.001$; reader 2: Spearman's rho, 0.75; $p < 0.001$).

The relation between the computed score and the four-point qualitative evaluation is shown for each reader in *figure 9.4*. The ICC for the qualitative evaluation and the computed score was 0.67 (95% CI, 0.45–0.81) for reader 1 and 0.64 (95% CI, 0.41–0.79) for reader 2.

Figure 9.5 shows the association between the computed score and the overall assessment of adequacy for both readers. For reader 1, the mean computed score for segments assessed as either inadequate or adequate cleansed segments was 5.0 and 6.4 respectively ($p = 0.001$). For reader 2 these values were 4.0 and 6.3 respectively ($p = 0.005$).

Discussion

We developed a computed quantitative scale to assess mucosal visibility during VCE, based on the colour intensities in the red and green channel of the tissue colour bar. The reproducibility of this scoring system was very good. We showed that the scoring system can be used to assess the overall quality of cleansing (experiment 1), as well as segmental quality of cleansing (experiment 2). There was strong agreement between the computed

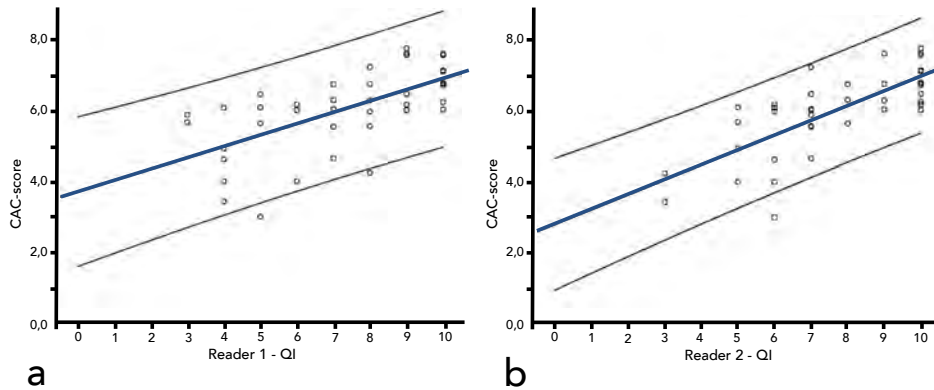


Figure 9.3: Correlation between the computed assessment of cleansing (CAC) score (y-axis) and the 10-point quantitative index (QI, x-axis) for reader 1 (a) and reader 2 (b). The outer lines denote the 95% confidence interval.

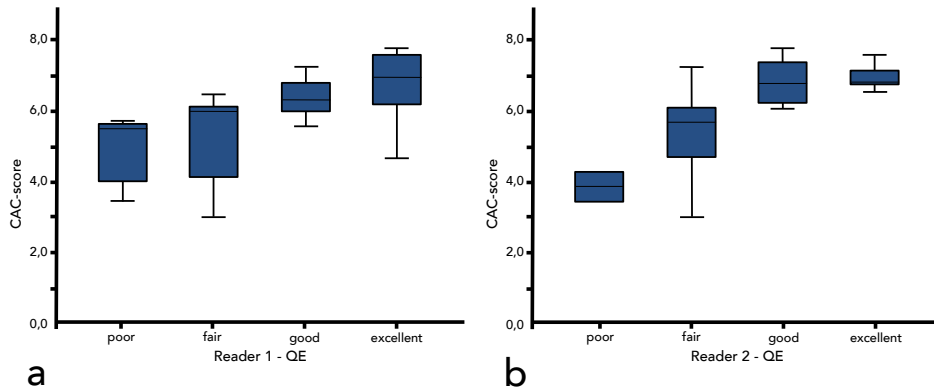


Figure 9.4: Boxplot presentation of the relationship between the computed assessment of cleansing (CAC) score (y-axis) and the 4-point qualitative index (QE, x-axis) for reader 1 (a) and reader 2 (b). The vertical line within the box indicated the median. The length of the box represents the intermediate 50% of cases, whereas the whiskers represent the 10th and 90th percentile. For studies in which reader 1 scored the quality of bowel cleansing as poor ($n = 6$), fair ($n = 8$), good ($n = 12$) or excellent ($n = 14$), the mean CAC scores were 4.7, 5.2, 6.3 and 6.8 respectively. For studies in which reader 2 scored the quality of bowel cleansing as poor ($n = 2$), fair ($n = 18$), good ($n = 15$) or excellent ($n = 5$), the mean CAC scores were 3.8, 5.4, 6.7 and 6.9 respectively.

scale and previously reported scales to assess the quality of small-bowel preparation (experiment 3). For this novel scoring system we propose the term Computed Assessment of Cleansing (CAC) score.

Our results show that an automated assessment of small-bowel cleansing is feasible. Our proposed grading-system is based on objective measurements of colour intensity of VCE images. Since this information is not readily available to end-users, we manually selected

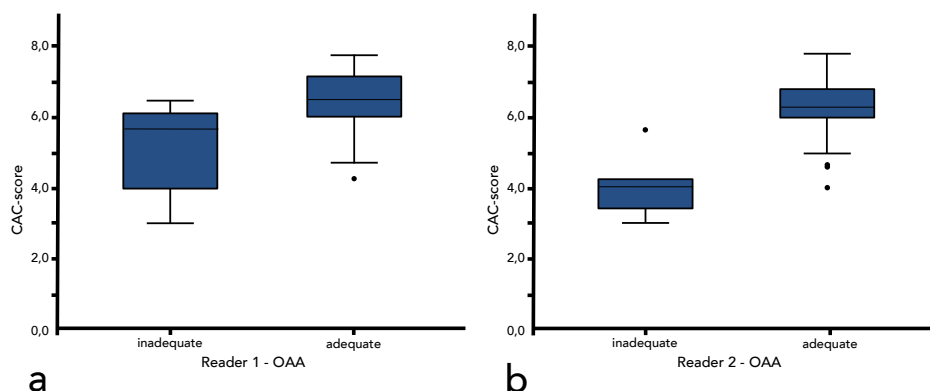


Figure 9.5: Boxplot presentation of the relationship between the computed assessment of cleansing (CAC) score (y-axis) and the overall assessment of adequacy (OAA, x-axis) for reader 1 (a) and reader 2 (b). The vertical line within the box indicated the median. The length of the box represents the intermediate 50% of cases, whereas the whiskers represent the 10th and 90th percentile. The dots represent outliers.

tissue colour bar segments, which comprise a computed summary of colour representations of individual VCE images and analysed of these segments using photo-editing software. When incorporated into VCE-reading software, these human interventions would be made redundant, resulting in a fully automated assessment of cleansing. We expect the results from such a scoring-system would be highly consistent. Potential measurements could include calculation of computed scores of time-based segments, total SBTT, or colonic transit. Additionally, an automated assessment of percentage of SBTT fulfilling predefined levels of visibility would be possible.

It is evident that mucosal visibility is mandatory for a reliable VCE investigation.^{4, 5}

The ability to diagnose intestinal disease can be severely restricted when intestinal contents obscure mucosal visibility. In analogy to colonoscopy, a gradation of mucosal visibility should therefore be a part of every VCE report, so that the reliability of the study can be assessed.⁷ As mucosal visibility often decreases towards the distal small intestine, the distribution of small-intestinal contamination should be part of such a grading system. Our proposed scoring system is able to give information on mucosal visibility of the total small bowel, as well of segments of every possible amount of time.

Only 10 VCE studies were included in the pilot study comparing the computed score with the three subjective scoring systems. To be able to compare four different scales to assess segmental mucosa visibility, 4 segments of 10 minutes duration per VCE study were isolated, resulting in 40 segments that were evaluated independently by two readers. The investigated segments therefore represent only 40 minutes of each included VCE study. However, these segments showed enough variation of cleanliness to validate our proposed score. Additionally, the proof of principle study comprised a total of 24 VCE studies and showed that reliable measurements are possible throughout the total

SBTT, regardless of indication. We only used the red and green channel as markers of intraluminal contamination. Although other (combinations of) colours might be used, we believe that a simple and transparent scoring system as the one we propose, and which is dependent of two variables only, is preferred over scoring systems using complex mathematical algorithms.

All our patients were prepared with 2 litres of polyethylene glycol solution, as has been custom in our hospital.²⁰ Our proposed scoring system should therefore also be validated in patients with different types of bowel preparation.

In conclusion, we showed that colour information of VCE studies could be used to compute a score for small-bowel mucosal visibility. Such a score circumvents subjective assessments as used in other grading systems. An objective score can be used to interpret the reliability of individual VCE studies and to compare different regimens of patient preparation. Additionally, such a score could be modified to assess colonic cleansing in colon capsule studies. A larger, prospective multicentre study is needed to assess the reliability of the computed cleansing score, and to investigate its association with diagnostic yield and its potential use in the comparison of different preparation strategies. Furthermore, the possibility of incorporating such calculations in VCE reader software and the use of the scoring system in capsule endoscopy of the colon should be evaluated.

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